

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SCIELE PHARMA, INC.,)	
ANDRX CORPORATION, ANDRX)	
PHARMACEUTICALS, INC. (N/K/A)	
WATSON LABORATORIES, INC.-)	
FLORIDA), ANDRX PHARMACEUTICALS,)	C.A. No. 09-037 (RBK)(JS)
L.L.C., ANDRX LABORATORIES (NJ),)	CONSOLIDATED
INC., ANDRX EU LTD., AND ANDRX)	
LABS, L.L.C.,)	
)	
Plaintiffs,)	
)	
v.)	
)	
LUPIN LTD., and)	
LUPIN PHARMACEUTICALS, INC.,)	
)	
Defendants.)	

SHIONOGI, INC.,)	
ANDRX CORPORATION, ANDRX)	
PHARMACEUTICALS, INC. (N/K/A)	
WATSON LABORATORIES, INC.-)	
FLORIDA), ANDRX PHARMACEUTICALS,)	
L.L.C., ANDRX LABORATORIES (NJ),)	
INC., ANDRX EU LTD., AND ANDRX)	
LABS, L.L.C.,)	C.A. No. 10-135 (RBK)(JS)
)	
Plaintiffs,)	
)	
v.)	
)	
MYLAN, INC., and)	
MYLAN PHARMACEUTICALS INC.,)	
)	
Defendants.)	

PLAINTIFFS' NOTICE OF 30(b)(6) DEPOSITION OF THE LUPIN DEFENDANTS

PLEASE TAKE NOTICE that Plaintiff Sciele Pharma, Inc., n/k/a Shionogi Inc., ("Shionogi") and Plaintiffs Andrx Corporation, Andrx Pharmaceuticals, Inc., n/k/a Watson Laboratories, Inc. - Florida, Andrx Pharmaceuticals, L.L.C., Andrx Laboratories (NJ), Inc., Andrx

EU Ltd., and Andrx Labs, L.L.C. (“Andrx”) (collectively “Plaintiffs”) will take the deposition by oral examination of Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively “Lupin”) pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure. The deposition will take place at the offices of WilmerHale LLP, 399 Park Avenue, New York, New York 10022, beginning at 9:30 a.m. on April 2, 2012, or at another agreed upon date and time, and will continue thereafter from day to day until completed. The topics of the deposition are set forth in Schedule A.

Pursuant to Rule 30(b)(6), Lupin is required to designate one or more officers, directors, employees or other persons who will testify on its behalf regarding the topics listed in Schedule A. Lupin is requested to provide Plaintiff’s counsel, as soon as reasonably possible, but no later than 10 business days before the deposition, a written designation of the name(s) and position(s) of the other person(s) who will be produced to testify on behalf of Lupin and, for each person designated, the topics set forth in the attached Schedule A as to which he or she will testify.

The deposition will be taken before a qualified Notary Public or before some other officer authorized by law to administer oaths. The deposition will be recorded by video and stenographic means. You are invited to attend and cross-examine.

RICHARDS, LAYTON & FINGER P.A.

/s/ Jason J. Rawnsley

Frederick L. Cottrell, III (#2555)
Steven J. Fineman (#4025)
Jason J. Rawnsley (#5379)
One Rodney Square
P.O. Box 551
Wilmington, DE 19899
(302) 651-7700
cottrell@rlf.com
fineman@rlf.com

Attorneys for the Andrx Plaintiffs

OF COUNSEL:

Gary E. Hood
POL SINELLI SHUGHART PC
161 North Clark, Suite 4200
Chicago, Illinois 60601
(312) 819-1900

Robyn H. Ast
POL SINELLI SHUGHART PC
100 S. Fourth Street, Suite 1000
St. Louis, Missouri 63102
(314) 622-6614

February 7, 2012

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Julia Heaney

Jack B. Blumenfeld (#1014)
Karen Jacobs Loudon (#2881)
Julia Heaney (#3052)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
kloudon@mnat.com

Attorneys for Plaintiff Shionogi

OF COUNSEL:

David A. Manspeizer
David Bassett
Peter Shen
Christopher R. Noyes
WILMER, CUTLER, PICKERING, HALE
AND DORR LLP
399 Park Ave
New York, NY 10022
(212) 263-8800

SCHEDULE A

DEFINITIONS

1. Any reference to a business entity includes all entities and persons acting on the business entity's behalf as well as all affiliates, divisions, parents, subsidiaries, and predecessors and successors thereof.

2. Any term defined in the singular also includes the plural and vice versa.

3. The term "analytical testing" shall be interpreted as set forth in Number 3 on page 2 of Lupin's Initial Disclosures.

4. The terms "and" and "or" shall be interpreted liberally as conjunctive, disjunctive, or both so that the fullest disclosure of information is achieved.

5. The term "ANDA" means Abbreviated New Drug Application.

6. The term "Andrx" means Andrx Corporation; Andrx Pharmaceuticals, Inc. (n/k/a Watson Laboratories, Inc. – Florida); Andrx Pharmaceuticals, L.L.C.; Andrx Laboratories (NJ), Inc.; Andrx EU Ltd.; and Andrx Labs., L.L.C., and each of their respective officers, directors, representatives, employees, agents, partners, corporate parents, subsidiaries, affiliates, predecessors, and successors.

7. The term "At-Risk Launch" means Lupin's importation and sale of Lupin's ANDA Metformin Products on or around September 30, 2011, and any subsequent importation and sale of Lupin's ANDA Metformin Products.

8. The term "communication" refers to all conversations, agreements, inquiries, or replies, whether in person, by telephone, in writing, or by means of electronic transmittal devices, and includes, but is not limited to, all correspondence, transmittal slips, memoranda, or notes.

9. The term “concerning” means in any way, directly or indirectly, regarding, considering, constituting, covering, defining, describing, involving, underlying, modifying, amending, confirming, mentioning, endorsing, recording, evidencing, pertaining to, referring to, reflecting, relating to, representing, supporting, qualifying, terminating, revoking, canceling, negating, or having any connection with the matter discussed.

10. The term “District Court Injunction” means the December 6, 2011 Order issued by the United States District Court for the District of Delaware enjoining Lupin from shipping or selling Lupin’s ANDA Metformin Products to any parties.

11. The term “document” means each and every writing, whether an original, a draft, or a copy, however produced or reproduced, and each and every thing from which information can be processed or transcribed, and includes, without limitation, all things meeting the definitions of “writings” and “recordings” as set forth in Fed. R. Evid. 1001. Any document without any marks such as initials, comments, or notations of any kind is not deemed to be identical to one without such marks and is to be produced and identified as a separate document. The term “document” is coextensive in scope with Rule 34 of the Federal Rules of Civil Procedure.

12. The term “drug product” has the meaning set forth in 35 U.S.C. § 156(f)(2).

13. The term “Extended Release Metformin Product” means any extended release drug product that includes metformin or a salt thereof as its active ingredient, regardless of the name or designation used in a particular document or thing.

14. The term “FDA” means the United States Food and Drug Administration.

15. The term “FORTAMET®” means the metformin hydrochloride product sold in the United States under approved New Drug Application No. 21-574.

16. The term “Lupin” means Lupin Ltd. and Lupin Pharmaceuticals, Inc., and each of their respective officers, directors, representatives, employees, agents, partners, corporate parents, subsidiaries, affiliates, predecessors, and successors.

17. The term “Notice Letter” means the letter dated December 3, 2008 from Lupin Ltd. to Andrx, regarding “FORTAMET – Metformin HCl ER Tablets (500 and 1000 mg) U.S. Patents Nos. 6,099,859, 6,495,162, 6,790,459, and 6,866,866 Notice of Paragraph IV Certification.”

18. The term “Lupin’s ANDA” means ANDA No. 90-692.

19. The term “Lupin’s ANDA Metformin Products” means the metformin products that are the subject of Lupin’s ANDA and which were shipped and/or sold as part of Lupin’s At-Risk Launch.

20. The term “Lupin’s Initial Disclosures” means Lupin’s initial disclosures pursuant to Fed. R. Civ. P. 26(a)(1) and any amendments thereto as required by Fed. R. Civ. P. 26.

21. The term “Lupin’s Label” means the FDA-approved label or package insert associated with Lupin’s ANDA Metformin Products.

22. The term “Lupin’s Paragraph IV Certification” means the patent certification filed by Lupin with the FDA pursuant to section 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act and § 314.95 of Title 21 of the Code of Federal Regulations in support of its ANDA with respect to metformin hydrochloride extended-release tablets USP, 500 mg and 1000 mg, as referenced in the Notice Letter.

23. The term “patents-in-suit” refers to U.S. Patent Nos. 6,099,859 (the “859 Patent”) and 6,866,866 (the “866 Patent”).

24. The term “payor/PBM” means managed care organizations, health plans and pharmacy benefit managers (acting individually, in connection with, or on behalf of other entities such as managed care organizations).

25. The term “person” or “persons” means any natural person or business, legal, or governmental entity or association.

26. The term “price” means any list price, average selling price, contract price, average manufacturer’s price (“AMP”), average wholesale price (“AWP”), best price (“BP”), retail or usual and customary (“U&C”) price, actual acquisition costs (“AAC”), estimated acquisition costs (“EAC”), federal upper limits (“FUL”), maximum allowable costs (“MAC”), wholesale acquisition costs (“WAC”), rebates, chargebacks, billbacks, return allowances, accruals, and discounts offered to payers, purchasers and/or prospective payers or purchasers.

TOPICS OF EXAMINATION

1. The decision by Lupin to develop an Extended Release Metformin Product including Lupin’s ANDA Metformin Products, or any other metformin product that might be A/B rated to FORTAMET®

2. The research and development of or leading to Lupin’s ANDA Metformin Products, including but not limited to Lupin’s research and development of Extended Release Metformin Products for which Lupin did not submit an ANDA or that did not show bioequivalence to FORTAMET®, and the identities and respective responsibilities or contributions of persons involved in that research and development, whether employees of Lupin or third parties.

3. The composition and/or formulation of Lupin’s ANDA Metformin Products, including but not limited to their chemistry, pharmacokinetics, and dissolution profile.

4. The use and/or intended use of each of the Lupin ANDA Metformin Products.

5. The research, design, and development leading to, and production of the Lupin ANDA Metformin Products, including without limitation any research and development relating to metformin, any research and development relating to FORTAMET ®, any research and development relating to generic versions of FORTAMET ®, any research and development relating to alternatives to FORTAMET ®, and the amount of money and time invested by Lupin in the research, design, and development of the Lupin ANDA Metformin Products.

6. The portions of Lupin's ANDA relating to chemistry, formulation, manufacturing, pharmacokinetics, or labeling, and any amendments or supplements thereto, including but not limited to their preparation, any correspondence or communications between Lupin and the FDA concerning these portions of Lupin's ANDA, any internal Lupin documents or communications concerning these portions of Lupin's ANDA, and the content of these portions of Lupin's ANDA.

7. The preparation and filing of Lupin's ANDA, including without limitation, all tests, analyses, studies, information, evaluations, and data contained or referenced in Lupin's ANDA, and/or relied upon by Mylan in preparing Lupin's ANDA, the decision to prepare and file Lupin's ANDA, any plans to supplement Lupin's ANDA, and the amount of money and time invested by Lupin in the preparation and filing of Lupin's ANDA.

8. Any consideration or analysis by Lupin of the commercial success of FORTAMET® or a generic Extended Release Metformin Product, including the sales or potential sales of such products by Lupin or other companies.

9. The facts and circumstances concerning Lupin's preparation and filing of Lupin's Paragraph IV Certification and the preparation and mailing of Lupin's Notice Letter.

10. In vitro and in vivo testing relating to the formulation or pharmacokinetics of Lupin's ANDA Metformin Products, including components thereof, and the identities and respective responsibilities of all individuals, whether employees of Lupin or third parties, having a role in the analytical testing of Lupin's ANDA Metformin Products.

11. Any clinical or preclinical testing concerning the dissolution profile and/or pharmacokinetic properties of Lupin's ANDA Metformin Products, whether or not submitted to the FDA, including but not limited to the identities and respective responsibilities of all individuals having a role in the testing of Lupin's ANDA Metformin Products whether employees of Lupin or third parties.

12. Lupin's Study 213-09 (LUP 0020062-110), including but not limited to all facts and circumstances surrounding the decision to conduct the study; the preparation of the protocol for the study; the identity of the formulation that was the subject of the study; the number of subjects chosen for the study; any power analysis performed regarding the number of subjects; dissolution data for the formulation administered in the study; lot numbers for the formulation administered in the study; manufacturing information for the formulation administered in the study; the caloric intake and caloric breakdown (by fat, carbohydrate, and protein) of food ingested by subjects in the study; rules or restrictions applied to subjects' diet, glucose intake, or exercise during the study; sampling intervals for the study; any reference standard used in the study; any cross validation performed in the study; and the purpose and statement of purpose of the study.

13. Any studies, tests, analyses, investigations, and/or evaluations done by or on behalf of or known to Lupin concerning the actual or potential market for Extended Release

Metformin Products, the clinical needs met by Extended Release Metformin Products, and the commercial success of FORTAMET®.

14. Lupin's proposed or actual marketing, distribution, and sales of an Extended Release Metformin Product, including analysis of the actual or potential market for FORTAMET® or Lupin's ANDA Metformin Products, Lupin's actual or contemplated plans and strategy to sell or market Lupin's ANDA Metformin Products, and any sales or market share projections or analyses for FORTAMET® or Lupin's ANDA Metformin Products, including the identities of individuals with responsibilities for the proposed marketing, distribution, and sales of an Extended Release Metformin Product whether employees of Lupin or third parties.

15. Lupin's domestic forecasting, budgeting, and financial or strategic planning relating to Lupin's ANDA Metformin Products, including any evaluations or criteria of profitability, profit studies, return-on-investment analyses, or pricing guidelines and including sales, market, budget, cost, margin or revenue forecasts or projections, business plans, marketing plans, consultant reports, or strategy or competitive analyses.

16. Knowledge, notice, and/or consideration by Lupin of the '859 and/or '866 Patents prior to the filing of Lupin's ANDA, including without limitation, the person(s) at Lupin who first learned of the '859 and/or '866 Patents, the circumstances through which they first learned of the '859 and/or '866 Patents, and any analysis of the '859 and/or '866 Patents.

17. Any patent policy in effect at Lupin at any time since 2005.

18. Any research or analysis performed by Lupin regarding the '859 and/or '866 Patents prior to the filing of Lupin's ANDA, including but not limited to, any efforts to compare Lupin's ANDA Metformin Products to the '859 and/or '866 Patents and all documents or any other evidence that Mylan considered in determining that the Lupin's ANDA Metformin

Products when marketed will not infringe one or more of the asserted claims of the '859 and/or '866 Patents.

19. All market projections and launch plans for Lupin's ANDA Metformin Products.

20. Any and all prior art searches, investigations, or analyses and results thereof, conducted or obtained by Lupin or on its behalf, relating to the validity, enforceability, enforcement, or claim construction of the '859 and/or '866 Patents, including without limitation the identity of any persons involved in, and any documents relating to, any such searches, investigations, or analyses.

21. All information relating to opinions of counsel, whether oral or in writing, concerning the '859 and/or '866 Patents, including when such opinion was requested, why such opinion was requested, from whom such opinion was requested, when it was received, by whom it was received, by whom it was evaluated, and who, if anyone, relied upon any such opinion.

22. Any licensing, supply, shipping, or other contractual agreement or understanding between Lupin and any other person or entity concerning Lupin's ANDA Metformin Products.

23. The preparation of Lupin's Notice Letter to Watson Pharmaceuticals, Inc. and Andrx.

24. Lupin's Label, including but not limited to decisions by Lupin as to what information to include on the label, whether to engage in in vitro or in vivo testing of Lupin's ANDA Metformin Products to support Lupin's Label, any consideration of whether to make or attempt to make alterations to its label based on alleged differences in pharmacokinetic or other parameters between Lupin's ANDA Metformin Products and FORTAMET®, and the identities of individuals having a role in the preparation or filing of proposed labeling with the FDA, whether employees of Lupin or third parties.

25. The At-Risk Launch of Lupin's ANDA Metformin Products, including but not limited to the importation, sale, offer for sale, distribution, or shipment by Lupin (or any party acting on Lupin's behalf) of Lupin's ANDA Metformin Products, as well as: the dates of sale, shipment, and receipt by the customer; the customer; the unit quantity of 500 mg and 1000 mg tablets sold and shipped, respectively; the price per unit quantity; the cost to Lupin of the sale; the profit, if any, earned by Lupin on the sale; any rebates or discounts provided in connection with the sale; any agreements with the customer concerning the sale and shipment; any other agreements with the customer concerning Lupin's ANDA Metformin Products; whether the sale was made pursuant to a mandatory substitution law; the formulary status given to Lupin's ANDA Metformin Products on or after the sale; and why the customer was selected for the sale or shipment.

26. Each sale and shipment of Lupin's ANDA Metformin Products, including, for each sale and shipment: the dates of sale, shipment, and receipt by the customer; the customer; the unit quantity of 500 mg and 1000 mg tablets sold and shipped, respectively; the price per unit quantity; the methodology used in setting any prices; the cost to Lupin of the sale; the profit, if any, earned by Lupin on the sale; any rebates or discounts provided in connection with the sale; any agreements with the customer concerning the sale and shipment; any other agreements with the customer concerning Lupin's ANDA Metformin Products; whether the sale was made pursuant to a mandatory substitution law; the formulary status given to Lupin's ANDA Metformin Products on or after the sale; and why the customer was selected for the sale or shipment.

27. The planning and execution of the At-Risk Launch, including but not limited to the selection of customers (retail, wholesale, or otherwise), communications with actual

customers, potential customers, or third parties related to the At-Risk Launch, and the extent to which Lupin provided advanced notice to customers or third parties that they would be involved in the At-Risk Launch.

28. The identities and respective responsibilities of all individuals who played a role in Lupin's At-Risk Launch, whether employees of Lupin or third parties.

29. The manufacture of Lupin's ANDA Metformin Products for Lupin's At-Risk Launch, including any manufacturing or production deficiencies at Lupin's factories or elsewhere at any time prior to the At-Risk Launch.

30. The decision to engage in the At-Risk Launch, including any analysis related to the benefits associated with the At-Risk Launch to Lupin and any analysis regarding Lupin's market share of Extended Release Metformin Product in comparison to other participants in the market including Shionogi and Andrx following the At-Risk Launch.

31. Documents or agreements associated with the At-Risk Launch, including but not limited to bills of lading, invoices, shipping records, contracts, or agreements with third parties including insurance or re-insurance agreements.

32. Communications with the FDA regarding Lupin's ANDA Metformin Products, Lupin's Label, and Lupin's At-Risk Launch.

33. Communications, contracts, or agreements with payors/PBMs, including communications, contracts or agreements regarding provisions for rebates based on the payor/PBM reimbursement volume of one or more Lupin Products.

34. Analysis by Lupin regarding the pricing of Lupin's ANDA Metformin Products associated with the At-Risk Launch, including but not limited to the impact on sales, prices, market share, and/or profit for Lupin's ANDA Metformin Products caused by sales of, or

distribution or marketing practices related to, Shionogi's or Andrx's products, as well as any response, analysis, strategy, or communication by Lupin related to such activities.

35. Financial information concerning Lupin's ANDA Metformin Products and Lupin's At-Risk Launch, including but not limited to: business plans; actual or forecasted projected gross and net sales; actual or forecasted projected costs and expenses associated with Lupin's ANDA Metformin Products; administrative or overhead expenses, costs of raw materials or API (active pharmaceutical ingredient), production costs, and royalties paid; method(s) used by Lupin to determine net profit margins and an explanation of all measures of profit used in connection with Lupin's ANDA Metformin Products, including gross profit, operating profit, and/or Contribution A; sharing of revenue or profits earned on Lupin's ANDA Metformin Products between the Lupin entities which are parties to this case and any other entities including any agreements concerning or reflecting such profit-sharing; and the reasons for any differences between Lupin's pre-At-Risk Launch projected, forecasted, planned, or budgeted revenue and profit from sales of Lupin's ANDA Metformin Products and post-At-Risk Launch actual revenue and profit.

36. Analysis by Lupin of the market for Lupin's ANDA Metformin Products, the marketing of said product, and/or the impact of the introduction of Lupin's ANDA Metformin Products on the market for FORTAMET®.

37. The District Court Injunction and any analysis supporting the arguments made by Lupin in opposing Shionogi's motion for preliminary injunction and Lupin's motions to stay the District Court Injunction, including but not limited to analysis concerning any harm, monetary or otherwise, that Lupin suffered or might suffer as a result of the District Court Injunction.

38. Lupin's activities concerning Lupin's ANDA Metformin Products and the At-Risk Launch following the District Court Injunction, including but not limited to production, importation for sale, offer for sale, or sale of Lupin's ANDA Metformin Products; communications with parties to whom Lupin had sold or shipped Lupin's ANDA Metformin Products as part of the At-Risk Launch; and the recall or decision not to recall any or all of Lupin's ANDA Metformin Products already in the market as a result of its At-Risk Launch.

39. Lupin's corporate organizational structure, including, but not limited to, the organizational structure of the business unit(s) (however designated) responsible for the conception, design, operation, function(s), research and development, manufacturing, sales and licensing, and/or marketing and advertising of Lupin's ANDA Metformin Products, the identification of its board of directors and corporate officers, and those of its affiliates and subsidiaries.

40. All documents produced by, and discovery responses served by, Lupin in connection with this lawsuit.

41. The locations and custodians of documents relevant to the topics of this Rule 30(b)(6) deposition notice.

42. The methodology, procedure, and efforts made by Lupin to identify, search for, locate, gather and produce documents responsive to Shionogi's discovery requests, including the identities of persons who were contacted to identify, search for, locate, and gather documents, the locations that were searched, and the location and custodians of the documents that were produced.

43. All steps taken by each person designated to testify about any of the matters set forth above to acquire all information known or reasonably available to Lupin about each such

matter, including all documents reviewed, discussed or prepared in connection with or in anticipation of the testimony by each designated witness, all communications with any person who provided any information about which testimony is provided or sought, and the identities of any individual(s) consulted to obtain information about which testimony is provided or sought.

44. Lupin's document retention or destruction policies in effect at any time since 2005.

CERTIFICATE OF SERVICE

I hereby certify that on February 6, 2012, electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following all registered participants.

I also certify that copies were caused to be served on February 6, 2012, upon the following in the manner indicated:

Richard D. Kirk, Esquire
Stephen B. Brauerman, Esquire
BAYARD, P.A.
222 Delaware Avenue, Suite 900
Wilmington, DE 19801
*Attorneys for Lupin Ltd. and Lupin
Pharmaceuticals, Inc.*

VIA ELECTRONIC MAIL

Douglass C. Hochstetler, Esquire
KELLEY DRYE & WARREN LLP
333 West Wacker Drive, 26th Floor
Chicago, IL 60606
*Attorneys for Lupin Ltd. and Lupin
Pharmaceuticals, Inc.*

VIA ELECTRONIC MAIL

Beth D. Jacob, Esquire
KELLEY DRYE & WARREN LLP
101 Park Avenue
New York, NY 10178
*Attorneys for Lupin Ltd. and Lupin
Pharmaceuticals, Inc.*

VIA ELECTRONIC MAIL

Karen A. Confoy, Esquire
Erica A. Helms, Esquire
STERN & WEINROTH PC
50 West State Street, Suite 1400
Trenton, NJ 08607
*Attorneys for Lupin Ltd. and Lupin
Pharmaceuticals, Inc.*

VIA ELECTRONIC MAIL

Richard Herrmann, Esquire
Mary B. Matterer, Esquire
MORRIS JAMES LLP
500 Delaware Avenue, Suite 1500
Wilmington, DE 19801
*Attorneys for Mylan Inc. and Mylan
Pharmaceuticals Inc.*

VIA ELECTRONIC MAIL

Timothy H. Kratz, Esquire
Robert L. Florence, Esquire
George J. Barry III, Esquire
MCGUIRE WOODS LLP
1230 Peachtree Street, N.E., Suite 2100
Atlanta, GA 30309
*Attorneys for Mylan Inc. and Mylan
Pharmaceuticals Inc.*

VIA ELECTRONIC MAIL

/s/ Julia Heaney

Julia Heaney (#3052)